

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated June 21, 2004 are respectfully requested.

I. Amendments

Claim 38 is amended to recite at least two of the plurality of resilient members being a sensor member. Support for this amendment can be found on page 3, lines 11-16, where it is stated that two or more tissue volumes can be monitored.

Claim 38 is further amended for clarity.

Claims 53 and 69 are amended to standardize terminology.

No new matter is added by way of these amendments.

II. Rejection under 35 U.S.C. §112, first paragraph

Claims 38-71 were rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that the specification fails to provide an adequate written description for each sensor member having a separate energy source.

These rejections are respectfully traversed.

A. Legal Standard for Written Description

According to MPEP 2163.02, an objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Unlike the "enablement" requirement, the "written description" requirement of 35 U.S.C. §112, first paragraph is not concerned with support commensurate with the breadth of the claims. The essential purpose of the written description requirement is to show the possession of the invention as of the filing date as a *prima facie* date of invention. *In re Smith*, 481 F.2d 910, 178 U.S.P.Q. 620, 623 (CCPA 1973). Accordingly, the specification is required to contain a statement that adequately describes the invention as claimed. However, the invention need not be described in *ipsis verbis* in order to satisfy the description requirement. See *In re Lukach, Olson, and Spurlin*, 169 U.S.P.Q. 795, 796 (CCPA 1971).

B Meeting the Legal Standard

Applicants first direct the Examiner to page 10, lines 9-14, where impedance measurement theory is described, specifically that an excitation current is applied across the tissue and measured. Further, on page 20, lines 3-5, and in Figure 4a, an embodiment is described where the sensing members can be connected to a power supply. Thus, it is clear that the sensor member can be coupled to an energy source.

Applicants further direct the Examiner to page 2, lines 25-29, page 14, lines 1-2, page 30, lines 24-25, and page 35, lines 1-3, where resilient members are described as either electrodes or sensor members based on their function. Thus, it is clear that disclosure relating to the electrodes may be applied to the sensor elements.

Applicants finally direct the Examiner to page 31, lines 19-20, where the electrodes are described as including sensing members. As seen on page 37, lines 7-11, the electrodes may be independently coupled to power sources. Thus, one of skill in the art would clearly recognize based on Applicants' disclosure that the sensing members may be independently coupled to different power sources.

Accordingly, Applicants submit that these teachings in the specification show that Applicants had possession of the invention as presently claimed at the time of filing.

III. Rejection under 35 U.S.C. §112, second paragraph.

Claims 38-71 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner objects to the recitation of the separate energy sources coupled to each sensor member and of electrodes coupled to at least one energy source is confusing.

The Examiner first states "it is not clear why a resilient member functioning solely as a sensor member would need to be connected to an energy source. The Examiner is respectfully directed to page 10, lines 9-14, where impedance measurement theory is described, specifically that an excitation current is applied across the tissue and measured. Thus, it is clear based on a reading of the specification that a resilient member functioning solely as a sensor member could still need to be connected to an energy source in order to measure impedance.

The Examiner further states "it is not clear if the 'separate energy source' connected to each sensor member is separate from the 'at least one energy source' which may be connected to the electrodes. Applicants have amended to claim to clarify the energy sources.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

IV. Rejection under 35 U.S.C. § 102

Claims 38-42 and 45-67 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gough *et al.* (U.S. Patent No. 5,683,384).

Claims 38-42 and 45-67 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gough *et al.* (U.S. Patent No. 5,800,484).

These rejections are respectfully traversed.

A. The Present Invention

The present invention relates to an ablation apparatus comprising (i) an elongated delivery device including a lumen, the elongated delivery device being maneuverable in

tissue, and (ii) an impedance array. The impedance array comprises a plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state. The resilient members define a sample volume in the deployed state. At least two of the plurality of resilient members are a sensor member and includes a sensor for determining impedance, where each sensor member is operatively connected to a separate impedance energy source. At least some of said resilient members are electrodes which can be coupled to at least one ablating energy source for ablating tissue when electrical energy is supplied to the electrodes from the source. The impedance array is effective to determine localized impedance.

B. The Prior Art

GOUGH ET AL. (THE '384 PATENT) relate to a multiple arm device including a primary arm with a longitudinal axis, and a secondary arm coupled to the primary arm. The secondary arm is configured to be deployed in a direction that is lateral to the longitudinal axis with at least one radius of curvature. The device may further include a multiplexer coupled to the primary antenna, the secondary antenna, and the energy source to multiplex between the primary and secondary antennas.

GOUGH ET AL. (THE '484 PATENT) describe an ablation apparatus comprising an introducer, two or more electrodes at least partially positioned in the introducer lumen, wherein each electrode is configured to be advanced from the introducer to define a volumetric ablation volume, and a porous fluid delivery member positioned on at least a portion of an exterior of at least one of the electrodes.

C. Analysis

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

C1. Rejection of the '384 patent

The '384 patent fails to teach at least two sensor members that includes a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source as in the present invention. The '384 patent makes no mention of a separate energy source for any of the deployable elements.

However, the Examiner states that "the Gough et al. disclosure inherently suggests the use of different energy sources for each electrode/sensor member."

The legal standard with respect to inherent anticipation is that "inherency may not be established by probabilities or possibilities. The mere fact that a certain thing *may result* from a given set of circumstances is insufficient to prove anticipation."

Contentental Can Co. v. Monsanto Co., 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991). *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA 1981).

This legal standard requires that the disclosure of at least two of the plurality of resilient members being a sensor member and including a sensor for determining impedance, where each sensor member is operatively connected to a separate impedance energy source, which is missing from the explicit disclosure of the '384 patent, be necessarily present in the '384 patent. The apparatus of the '384 patent includes electrodes that may be switched between energy sources (i.e. RF and microwave sources). It does not necessarily follow that each electrode is connected to a separate energy source much less that the apparatus include at least two sensor members, each coupled to a separate energy source for determining impedance based on this disclosure as the electrodes could be connected to the same source.

C2. Rejection of the '484 patent

The '484 patent fails to teach at least two sensor members that includes a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source as in the present invention. The '484 patent makes no mention of a separate energy source for any of the deployable elements.

The disclosure of the '484 patent does not inherently anticipate the claimed method, for all the reasons given above in section C1.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met. Withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,



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